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Office of Pesticide Programs
Environmental Protection Agency
Docket Center (EPA/DC), (28221T),
1200 Pennsylvania Ave. NW.,
Washington, DC 20460-0001.

Re: Draft Human Health Risk Assessment for Permethrin. Docket No: EPA-HQ-OPP-2011-0039

We are submitting these comments in response to the U.S. Environmental Protection Agency's (EPA) draft risk assessment on the human health impacts of permethrin. Permethrin is a pyrethroid insecticide that has a wide variety of uses from agriculture to turf, mosquito and residential uses. People can be exposed via food and water, treated turf, treated pets, mosquito adulticiding, and treated fabrics. Studies find that outdoor air, indoor air, and settled dust may constitute significant exposure sources, with dermal contact and indirect dust ingestion important exposure pathways.¹ Permethrin is associated with neurological toxicity, including neurodevelopmental disorders. A recent study reports that synthetic pyrethroids like permethrin can negatively affect neurobehavioral development in children by age six.² Associations with attention deficit hyperactivity disorder (ADHD) in children and young teens³ and increased risk of autism⁴ have been observed.

Permethrin has also been linked to endocrine and reproductive effects. In fact, permethrin is recognized as a potential endocrine disruptor in the European Union based on the inhibition of androgen binding in vitro.⁵ Permethrin was also found to have mutagenic effects in three tests with human cell cultures, resulting in an increase in chromosome aberrations, chromosome fragments, and DNA lesions.⁶ Currently, EPA classifies permethrin as

¹ Hermant M, Blanchard O, Perouel G, et al. 2017. Environmental Exposure of the Adult French Population to Permethrin. *Risk Anal.* doi: 10.1111/risa.12866

² Viel, JF, Rouget, F et al. 2017. Behavioural disorders in 6-year-old children and pyrethroid insecticide exposure: the PELAGIE mother-child cohort. *Occup and Environ Med.* 74(4) <http://dx.doi.org/10.1136/oemed-2016-104035>

³ Wagner-Schuman, M, Richardson, JR, Auinger, P et al. 2015. Association of pyrethroid pesticide exposure with attention-deficit/hyperactivity disorder in a nationally representative sample of U.S. children. *Environmental Health.* 14:44 <https://doi.org/10.1186/s12940-015-0030-y>

⁴ Shelton, J, Geraghty, E, Tancredi, Dj et al. 2014. Neurodevelopmental Disorders and Prenatal Residential Proximity to Agricultural Pesticides: The CHARGE Study. *Environ Health Perspect*; DOI:10.1289/ehp.1307044

⁵ European Commission, DG ENV. 2002. Endocrine disruptors: study on gathering information on 435 substances with insufficient data. Final Report. Available at http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#report2

⁶ Surrallés, J. et al. 1995. The suitability of the micronucleus assay in human lymphocytes as a new biomarker of excision repair. *Mut. Res.* 342:43-59.

“Likely to be Carcinogenic to Humans” based on observations of tumors in male and female mice.⁷

With the above neurological and non-neurotoxic adverse health associations for permethrin (especially cancer), we are troubled that the agency is moving forward to reduce the Food Quality Protection Act (FQPA) safety factor for children. It is not appropriate to reduce a safety factor for any substance that is classified as a “Likely” carcinogen. Given permethrin’s cancer classification, there should have been a cancer aggregate assessment, which the agency indicated it did not conduct at this time.

Mosquito Adulticide Exposure Assessment

An increased risk of neurological disorders in areas where mosquito spraying is common has been reported. One study examining rates of autism spectrum disorder and developmental delay diagnoses in an area that employs yearly aerial pyrethroid pesticide applications to combat mosquito-borne diseases finds that children were 37 percent more likely to have autism or developmental delays.⁸ EPA conducted a residential assessment for mosquito adulticide use for both ground and aerial applications. Modeling data was utilized to determine how much pesticide residue is deposited on residential lawns, but it is unclear whether an assessment of indoor residues was considered. Indoor residues from mosquito adulticiding are possible and should be assessed as part of a residential assessment. For instance, in a study examining the relationship between prenatal exposure to indoor pesticides and infant growth and development in urban families,⁹ researchers at the Mount Sinai School of Medicine found higher than expected levels of pyrethroid metabolites in sample urine (compared with previous NHANES data) which, according to the researchers, may be attributed to higher exposures resulting from mosquito spray programs in the subjects’ communities. Given that the half-lives of pyrethroids are relatively short, high levels of metabolites in the urine indicate continuous exposures.

FQPA Safety Factor

The purpose of the FQPA margin of safety factor is “to protect infants and children, taking into account the potential for pre- and post-natal toxicity.” 21 USC §346a (b)(2)(C). It is known that children face unique hazards from pesticide exposure.¹⁰ We disagree with EPA’s decision to reduce the FQPA safety factor to 3x for children under six years of age and 1X for persons over six years old. FQPA allows EPA to “use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for

⁷ USEPA. 2017. Permethrin: Human Health Draft Risk Assessment for Registration Review. Office of Pesticide Programs. Washington DC

⁸ Hicks, S, Wang, M, Fry, K, et al. 2017. Neurodevelopmental Delay Diagnosis Rates Are Increased in a Region with Aerial Pesticide Application. *Front. Pediatr.* doi.org/10.3389/fped.2017.00116

⁹ Berkowitz GS, Obel J, Deych E, Lapinski R, Godbold J, Liu Z, et al. 2003. Exposure to indoor pesticides during pregnancy in a multiethnic, urban cohort. *Environ Health Perspect* 111:79–84.

¹⁰ National Research Council, National Academy of Sciences. 1993. Pesticides in the Diets of Infants and Children, National Academy Press, Washington, DC. 184-185.

infants and children.” There must be no level of acceptable risk, given that permethrin is a likely human carcinogen. Permethrin is also a possible endocrine disruptor. EPA’s tier 1 screening indicates that “based on the available in vitro and mammalian in vivo data, there appears to be a potential interaction with the androgen pathway in mammals.”¹¹ The agency believes the current risk assessment is protective of androgen-mediated effects, but given the inadequacies of EPA’s endocrine disruption program,¹² and the evidence cited above, EPA’s risk estimates are not certain enough to allow a reduction of the FQPA safety factor at this time.

Conclusion

Permethrin is a commonly used insecticide especially in residential settings. It is also one of the go-to adulticides used in many mosquito spray programs. While EPA may feel confident in its assessment, the epidemiological data continues to report adverse effects in children following exposure to pyrethroids like permethrin in indoor environments and from mosquito spraying. Given its neurotoxicity, carcinogenic classification, and potential for endocrine disruption, a reduction in the FQPA safety factor for children is not warranted. We hope the agency will consider these comments and retain a 10X safety factor.

Respectfully,



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Science and Regulatory Director

¹¹ USEPA. 2015. EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals. Chemical: Permethrin. Office of Chemical Safety and Pollution Prevention. Washington DC.

¹² National Academy of Science. 2017. [Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals](https://www.nap.edu/catalog/24758/application-of-systematic-review-methods-in-an-overall-strategy-for-evaluating-low-dose-toxicity-from-endocrine-active-chemicals) <https://www.nap.edu/catalog/24758/application-of-systematic-review-methods-in-an-overall-strategy-for-evaluating-low-dose-toxicity-from-endocrine-active-chemicals>